



IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Group Art Unit Not yet assigned

In re

Patent Application of

G. Ian Rowlandson et al.

Application No.: 10/824,983

Confirmation No.: Not yet assigned

Filed: April 15, 2004

Examiner: Not yet assigned

"SYSTEM AND METHOD FOR  
ASSESSING A PATIENT'S RISK OF  
SUDDEN CARDIA DEATH"

I, Kate Jochman, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date of my signature.

Signature

Date of Signature

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 CFR §1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08A. Copies of the foreign and non-patent references are attached. Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

Raye L. Daugherty  
Reg. No. 47,933

File No. 039199-9555-00  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue  
Milwaukee, Wisconsin 53202-4108  
(414) 271-6560



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO

## Complete if Known

## PATENT INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

7

Application Number	10/824,983
Filing Date	April 15, 2004
First Name Inventor	G. Ian Rowlandson
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	039199-9555-00

## U.S. PATENT DOCUMENTS

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	4,589,420	Adams et al.	5/20/1986
	4,457,315	Bennish	7/3/1984
	5,201,321	Fulton	4/13/1993
	4,854,327	Kunig	8/8/1989
	5,025,795	Kunig	6/25/1991
	4,989,610	Patton et al.	2/5/1991
	4,977,899	Digby et al.	12/18/1990
	4,958,641	Digby et al.	9/25/1990
	4,928,690	Heilman et al.	5/29/1990
	4,860,762	Heumann et al.	8/29/1989
	4,679,144	Cox et al.	7/7/1987
	4,432,375	Angel et al.	2/21/1984
	4,422,459	Simson	12/27/1983
	4,202,340	Langer et al.	5/13/1980
	5,117,834	Kroll et al.	6/2/1992
	4,492,235	Sitrick	1/8/1985
	4,458,692	Simson	7/10/1984
	4,458,691	Netravali	7/10/1984

Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	10/824,983
		<b>Filing Date</b>	April 15, 2004
		<b>First Name Inventor</b>	G. Ian Rowlandson
		<b>Group Art Unit</b>	Not yet assigned
		<b>Examiner Name</b>	Not yet assigned
(use as many sheets as necessary)		<b>Attorney Docket Number</b>	039199-9555-00
Sheet	2	of	7

U.S. PATENT DOCUMENTS				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		4,974,598	John	12/4/1990
		5,117,833	Albert et al.	6/2/1992
		5,000,189	Throne et al.	3/19/1991
		4,519,395	Hrushesky	5/28/1985
		4,136,690	Anderson et al.	1/30/1979
		5,570,696	Arnold et al.	11/5/1996
		5,819,741	Karlsson et al.	10/13/1998
		5,343,870	Gallant et al.	9/6/1994
		6,453,191	Krishnamachari	9/17/2002
		4,802,491	Cohen et al.	2/7/1989
		5,935,082	Albrecht et al.	8/10/1999
		5,148,812	Verrier et al.	9/22/1992
		5,265,617	Verrier et al.	11/30/1993
		5,437,285	Verrier et al.	8/1/1995
		5,560,370	Verrier et al.	10/1/1996
		5,921,940	Verrier et al.	7/13/1999
		6,169,919	Nearing et al.	1/2/2001
		4,896,677	Kaneko et al.	1/30/1990
		4,732,157	Kaplan et al.	3/22/1988
		4,972,834	Begemann et al.	11/27/1990
		5,042,497	Shapland	8/27/1991
		5,188,116	Pommrehn et al.	2/23/1993

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	10/824,983
		<b>Filing Date</b>	April 15, 2004
		<b>First Name Inventor</b>	G. Ian Rowlandson
		<b>Group Art Unit</b>	Not yet assigned
		<b>Examiner Name</b>	Not yet assigned
<i>(use as many sheets as necessary)</i>		<b>Attorney Docket Number</b>	039199-9555-00
Sheet	3	of	7

U.S. PATENT DOCUMENTS				
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,277,190	Moulton	1/11/1994
		3,554,187	Glassner et al.	1/12/1971
		4,802,491	Cohen et al.	2/7/1989
		4,924,875	Chamoun	5/15/1990
		4,974,162	Siegel et al.	11/27/1990
		3,902,479	Chaumet	9/2/1975
		4,170,992	Dillman	10/16/1979
		4,603,703	McGill et al.	8/5/1986
		4,665,485	Lundy et al.	5/12/1987
		3,759,248	Valiquette	9/18/1973
		4,316,249	Gallant et al.	2/16/1982
		4,938,228	Righter et al.	7/3/1990
		4,951,680	Kirk et al.	8/28/1990
		4,955,382	Franz et al.	9/11/1990
		4,832,038	Arai et al.	5/23/1989
		4,475,558	Brock	10/9/1984
		4,616,659	Prezas et al.	10/14/1986
		3,658,055	Abe et al.	4/25/1972
		3,821,948	King	7/2/1974
		3,952,731	Worstencroft	4/27/1976
		4,181,135	Andresen et al.	1/1/1980
		4,417,306	Citron et al.	11/22/1983

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO

Complete if Known

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT***(use as many sheets as necessary)*

Sheet

4

of

7

**Application Number**

10/824,983

**Filing Date**

April 15, 2004

**First Name Inventor**

G. Ian Rowlandson

**Group Art Unit**

Not yet assigned

**Examiner Name**

Not yet assigned

**Attorney Docket Number**

039199-9555-00

**U.S. PATENT DOCUMENTS**

Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		5,423,878	Franz	6/13/1995
		5,253,650	Wada	10/19/1993
		4,124,894	Vick et al.	11/7/1978
		4,979,510	Franz et al.	12/25/1990
		5,020,540	Chamoun	6/4/1991
		4,583,553	Shah et al.	4/22/1986
		4,680,708	Ambos et al.	7/14/1987
		4,796,638	Sasaki	1/10/1989
		5,092,341	Kelen	3/3/1992
		5,109,862	Kelen et al.	5/5/1992
		5,570,696	Arnold et al.	11/5/1996
		5,323,783	Henkin et al.	6/28/1994
		5,234,404	Tuttle et al.	8/10/1993
		5,010,888	Jadvar et al.	4/30/1991

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/824,983
		<b>Filing Date</b>	April 15, 2004
		<b>First Name Inventor</b>	G. Ian Rowlandson
		<b>Group Art Unit</b>	Not yet assigned
		<b>Examiner Name</b>	Not yet assigned
Sheet 5 of 7	<b>Attorney Docket Number</b>	039199-9555-00	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	DE	2604460	Michael S. Lampadius	8/11/1977		
	DE	3303104	Belorussky Nauchno-Issledovatel'sky Institut Kardiologii	8/2/1984		
	DE	4024360	Transformatoren und Rontgenwerk GmbH	3/21/1991		
	EP	0080821	Datamedix, Inc.	6/8/1983		
	FR	2539978	Belorussky Nauchno-Issledovatel'sky Institut Kardiologii	8/3/1984		
	UK	2070871	Anderson et al.	9/9/1981		
	WO	WO81/02832	Datamedix, Inc.	10/15/1981		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc. ), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		Speranza et al., 'Beat-to-beat measurement and analysis of the R-T interval in 24 h ECG Holter recordings,' Med and Biol Eng & Comput, 1993, 31, pp. 487-494.
		Narayanaswamy et al., 'Selective beat signal averaging and spectral analysis of beat intervals to determine the mechanisms of premature ventricular contractions,' University of Oklahoma Health Sciences Center, May 1993, pp. 81-84.
		Laks et al., 'ECG computer program developed for a retrospective and prospective study of the Pardee T wave,' Department of Medicine, UCLA School of Medicine, Harbor-UCLA Medical Center, Torrance, CA, 1992, pp. 365-368.
		Makarov et al., 'Holter monitoring in the long QT syndrome of children and adolescents,' Cor Vasa, 1990, 32(6), pp. 474-483.
		Navarro-Lopez et al., 'Isolated T wave alternans elicited by hypocalcemia in dogs,' Electrocardiology, 1978, 11(2), pp. 103-108.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/824,983
		<b>Filing Date</b>	April 15, 2004
		<b>First Name Inventor</b>	G. Ian Rowlandson
		<b>Group Art Unit</b>	Not yet assigned
		<b>Examiner Name</b>	Not yet assigned
Sheet 6 of 7	<b>Attorney Docket Number</b>	039199-9555-00	

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc. ), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		Little et al., 'Torsade de Pointes and T-U wave alternans associated with arsenic poisoning,' Pace, 1990, 13, pp. 164-170.
		Weintraub et al., 'The congenital long QT syndromes in childhood,' Journal of the American College of Cardiology, September 1990, 16(3), pp. 674-680.
		Bibler et al., 'Recurrent ventricular tachycardia due to pentamidine-induced cardiotoxicity,' Chest, December 1988, 94(6), pp. 1303-1306.
		Ahnve et al., 'Circadian variations in cardiovascular parameters during sleep deprivation, A noninvasive study of young healthy men,' European Journal of Applied Physiology, 1981, 46, pp. 9-19.
		Surawicz, 'ST-segment, T-wave, and U-wave changes during myocardial ischemia and after myocardial infarction,' Canadian Journal of Cardiology, Supplement A, July 1986, pp. 71A-84A.
		Stroobandt et al., 'Simultaneous recording of atrial and ventricular monophasic action potentials: monophasic action potential duration during atrial pacing, ventricular pacing, and ventricular fibrillation,' Pace, July-August 1985, 8, pp. 502-511.
		Sharma et al., 'Romano-Ward prolonged QT syndrome with intermittent T wave alternans and atrioventricular block,' American Heart Journal, 1981, pp. 500-501.
		Navarro-Lopez et al., 'Isolated T wave alternans,' American Heart Journal, 1978, pp. 369-374.
		Mitsutake et al., 'Usefulness of the Valsalva Maneuver in management of the long QT syndrome,' Circulation, 1981, 63(5), pp. 1029-1035.
		Nearing et al., 'Personal computer system for tracking cardiac vulnerability by complex demodulation of the T wave,' American Physiological Society, 1993, pp. 2606-2612.
		Joyal et al., 'ST-segment alternans during percutaneous transluminal coronary angioplasty,' Division of Cardiology, Department of Medicine, University of Florida and the Veterans Administration Medical Center, June 1984, pp. 915-916.
		Schwartz et al., 'Electrical alternation of the T-wave: clinical and experimental evidence of its relationship with the sympathetic nervous system and with the long Q-T syndrome,' American Heart Journal, January 1975, 89(1), pp. 45-50.
		Schwartz, 'Idiopathic long QT syndrome: progress and questions,' American Heart Journal, February 1985, 109(2), pp. 399-411.
		Verrier et al., 'Electrophysiologic basis for T wave alternans as an index of vulnerability to ventricular fibrillation,' Journal of Cardiovascular Electrophysiology, May 1994, 5(5), pp. 445-461.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute of form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	10/824,983
		<b>Filing Date</b>	April 15, 2004
		<b>First Name Inventor</b>	G. Ian Rowlandson
		<b>Group Art Unit</b>	Not yet assigned
		<b>Examiner Name</b>	Not yet assigned
<i>(use as many sheets as necessary)</i>		<b>Attorney Docket Number</b>	039199-9555-00
Sheet	7	of	7

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc. ), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
		Verrier et al., 'Behavioral states and sudden cardiac death,' Pace, September 1992, 15, pp. 1387-1393.
		Turitto et al., 'Alternans of the ST segment in variant angina,' Chest, March 1988, 93(3), pp. 587-591.
		Ring et al., 'Exercise-induced ST segment alternans,' American Heart Journal, May 1986, 111(5), pp. 1009-1011.
		Wayne et al., 'Exercise-induced ST segment alternans,' Chest, May 1983, 83(5), pp. 824-825.
		Verrier et al., 'Ambulatory electrocardiogram-based tracking of T wave alternans in postmyocardial infarction patients to assess risk of cardiac arrest or arrhythmic death,' Journal of Cardiovascular Electrophysiology, July 2003, 14(7), pp. 705-711.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. Patent and Trademark Office, Washington, DC 0231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box Alexandria, VA 22313-1450.